RCE/1616

MS RCE
PATENT
3893-0112P

IN THE U.S. PATENT AND TRADEMARK OFFICE

Applicant:	Gunnar GRUE-SORENSEN et al.	Conf.:	2538
Appl. No.:	09/787,548	Group:	1616
Filed:	March 20, 2001	Examiner:	B. BADIO
For:	THERAPEUTIC USE OF VITAMIN D ANALOGUES		

REQUEST FOR CONTINUED EXAMINATION
UNDER 37 C.F.R. § 1.114

MS RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

June 7, 2004

Sir:

This is a "Request for Continued Examination" under 37 C.F.R. § 1.114, the provisions of which do not apply to:

(1) A provisional application; (2) An application for a utility or plant patent filed under 35 U.S.C. 111(a) before June 8, 1995; (3) An international application filed under 35 U.S.C. §363 before June 8, 1995; (4) An application for a design patent; or (5) A patent under reexamination.

Submission of an RCE is limited to an application in which prosecution is closed; e.g. final rejection, Ex Parte Quayle; or notice of allowability

☒ This Request for Continued Examination is being filed prior to the earliest of:

(1) Payment of the issue fee, unless a petition under § 1.313 is granted; (2) Abandonment of the application; or (3) The filing of a notice of appeal to the U.S. Court of Appeals for the Federal Circuit under 35 U.S.C. § 141, or the commencement of civil action under 35 U.S.C. §§ 145 or 146, unless the appeal or civil action is terminated.

☐ The enclosed document is being transmitted via the Certificate of Mailing provisions of 37 C.F.R. § 1.8.

☐ The enclosed document is being transmitted via facsimile.

☒ **Submission Required under 37 C.F.R. § 1.114:**

☐ Do **NOT** enter the After Final Amendment(s) previously filed on under 37 C.F.R. § 1.116.

Enter as part of the present submission:

☒ The After Final Amendment(s) previously filed on February 20, 2004, under 37 C.F.R. § 1.116 but unentered, in the present application.

☐ Arguments in the Appeal Brief or Reply Brief previously filed on .

☐ A Reply Under Rule 1.111, attached hereto. Claim fee(s) are calculated as set forth below:

	TOTAL NUMBER OF CLAIMS **PREVIOUSLY** PAID FOR	TOTAL NUMBER OF CLAIMS BEING FILED HEREWITH	**NUMBER EXTRA**	**Large Entity**		**Small Entity**	
				Rate	Fee	Rate	Fee
Total Claims	20	=		X 18	$	X 9	$
Independent Claims	3	=		X 86	$	X 43	$
☐ **FIRST** PRESENTATION OF A MULTIPLE DEPENDENT CLAIM				290	$	145	$
			TOTAL CLAIM FEE(S)			**$0.00**	

☐ An Information Disclosure Statement (IDS) and PTO-1449 form(s) is/are attached hereto for the Examiner's consideration.

☒ Other: Submission Under 37 C.F.R. 1.114

☐ **Miscellaneous**

☐ Suspension of action on the above-identified application is requested under 37 C.F.R. § 1.103(c) for a period of ( ) months. (Period of suspension shall not exceed 3 months.)

☒ **Fees**

The required fee under 37 C.F.R. § 1.17(e) as required by 37 C.F.R. § 1.114 when the RCE is filed, is enclosed herewith:

☐ $385.00 - small entity

☒ $770.00 - large entity

☐ The applicant(s) hereby petition(s) for an extension of ( ) month(s) pursuant to 37 C.F.R. §§ 1.17 and 1.136(a). The fee has been calculated as shown below:

☐ NO extensions of time have been previously obtained in the prior application. Thus, a fee of $0.00 is required for the full period of the above-requested extension of time.

☐ An extension of ( ) month(s) was previously requested and paid for on in the instant application. Thus, a fee of $0.00 is required to obtain an additional ( ) month(s) extension.

☐ The fee of $130.00 under 37 C.F.R. § 1.17(i) for suspension of action is enclosed.

☒ Enclosed is(are) check(s) in the total amount of $770.00 for the applicable filing fee, additional claims fee, suspension fee, and/or extension fees.

☐ Please charge Deposit Account No. 02-2448 in the amount of $0.00. A triplicate copy of this sheet is attached.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

BIRCH, STEWART, KOLASCH & BIRCH, LLP

By _____
Andrew D. Meikle, #32,868

P.O. Box 747
Falls Church, VA 22040-0747
(703) 205-8000

ADM:gmh
3893-0112P

Attachment(s)

(Rev. 02/12/2004)

PATENT
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SUBMISSION UNDER 37 C.F.R. 1.114

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

June 7, 2004

Sir:

This Submission includes a Request for a Personal Interview with the Patent Examiner before any Office Action issues, and a brief explanation of a Declaration submitted in support of the patentability of the present claims.

Request for Personal Interview with Patent Examiner before first Office Action

It is respectfully requested that the Patent Examiner refrain from issuing any Office Action until applicants' representative can arrange a personal Interview with the Examiner. Applicants' representative will attempt to contact the Examiner within about one (1) month from the filing of this Request for Continued Examination (RCE) and Submission, i.e. by about July 7, 2004.

Submission of 132 Declaration Supporting Patentability of Claims

In order to further support the patentability of the present claims, enclosed is a Declaration under 37 C.F.R. 1.132 (herein after the "Nielsen Declaration"). The Nielsen Declaration establishes the following three points:

[1] First, hyperparathyroidism (caused by a raised level of parathyroid hormone) can cause the bone related disease "osteomalacia". Osteomalacia and osteoporosis differ in their symptoms. Therefore, the bone related disease state caused by hyperparathyroidism cannot be described as "osteoporosis" from a scientific point of view.

[2] Secondly, osteomalacia (caused by hyperparathyroidism) is treated differently than is osteoporosis. Osteomalacia is treated by the suppression of parathyroid hormone (consistent with the treatment of hyperparathyroidism). Osteoporosis is not treated by the suppression of parathyroid hormone, but rather osteoporosis is treated by changing the balance between anabolic and catabolic processes in the bone, e.g. by inhibiting bone resorption.

[3] Thirdly, the Neilsen Declaration states in paragraph (5) that the FDA Guidelines do not accept the suppression of parathyroid hormone (used to treat hyperparathyroidism and osteomalacia) as a surrogate parameter for the efficacy of a new

drug used to treat osteoporosis. In contrast, the FDS Guidelines require data regarding the effects of an osteoporosis treatment drug on bone quality, such as bone mass, bone strength, and bone architecture.

Discussion Points for Interview

At the Interview, applicants' representative would like to discuss the Neilsen Declaration and the scope of the prior art. In this regard, it is noted that the prior art includes Calverley '475 (WO 91/15475) and Calverley '629 (USP 5,374,629 corresponding to Calverley '475). Calverley '475/ '629 disclose compounds used to treat hyperparathyroidism which overlap with the compounds used in the osteoporosis treatment method claims of the present application. However, Calverley '475/ '629 fails to disclose or suggest the use of the compounds for the treatment of osteoporosis.

As noted above, the Neilsen Declaration establishes the following facts:

[1] hyperparathyroidism may lead to osteomalacia, but does not lead to osteoporosis;

[2] hyperparathyroidism and osteomalacia are treated by the use of compounds to suppress the parathyroid hormone which contrasts with the treatment of osteoporosis by using compounds

that change the balance between anabolic and catabolic processes in the bone; and

[3] the FDA Guidelines do not accept parathyroid hormone suppression as a surrogate parameter for the efficacy of a new osteoporosis treatment compound.

Consequently, a significant achievement by the inventors of the present application was to discover that the compounds employed in the described treatment method exhibit advantageous bone anabolic effects useful to treat osteoporosis.

In view of the above, it is clear that Calverley '475/ '629 fail to disclose or suggest the use of the described compounds for changing anabolic and catabolic processes in the bone in order to treat osteoporosis, since the disclosure is limited to describing the use of the compounds for the suppression of parathyroid hormone in order to treat hyperparathyroidism, or possibly osteomalacia.

If any questions arise regarding the above matters, please contact Applicant's representative, Andrew D. Meikle (Reg. No. 32,868), in the Washington Metropolitan Area at the phone number listed below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees

required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

BIRCH, STEWART, KOLASCH & BIRCH, LLP

By _____
Andrew D. Meikle, #32,868

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Enclosures: Neilsen Declaration Under 37 C.F.R. 1.132